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# Epidemiology

## Version 5.3

Corrected, Updated, Lighter

**PLAB 1 Keys is for PLAB-1 and UKMLA-AKT (Based on the New MLA Content-Map)**

**With the Most Recent Recalls and the UK Guidelines**

**ATTENTION: This file will be updated online on our website frequently!**

**(example: Version 2.1 is more recent than Version 2, and so on)**

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# Important Calculations

| | |
|---|---|
| **Incidence** | Number of **NEW** cases within population at risk |
| **Prevalence** | Number of **NEW** + **OLD** cases within population at risk |
| **Absolute Risk (AR)** | Number of events ÷ Population within that group |
| **Relative Risk (RR)** | **Exposed ÷ Non-exposed OR (ART ÷ ARC)**<br>(AR **Treatment** group ÷ AR **Control** group) |
| **Absolute Risk Reduction (ARR)** | AR **Control (Placebo)** group - AR **Test (Treatment)** group<br>(ARC – ART) |
| **Relative Risk Reduction (RRR)** | 1 – RR (Relative Risk) OR:<br>(ARC – ART) / ARC |
| **Sensitivity** | True Positive ÷ (True Positive + False Negative) = A ÷ (A+C) |
| **Specificity** | True Negative ÷ (True Negative + False Positive) = D ÷ (D+B) |

***These calculations are explained with examples in the following notes.***

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**Key 1**

# The Number Needed to Treat (NNT)

- **The NNT is the average number of patients who need to be treated to prevent one additional bad outcome.**
- **(eg, the number of patients that need to be treated for one of them to benefit compared with a control in a clinical trial).**
- **It is also defined as the inverse of the absolute risk reduction (ARR)**

  **i.e., NNT = 1/ARR**

**Example (1)**

30 patients needed to use drug (X) to prevent lung cancer compared to a placebo drug. This study is continued for 15 years. What is the NNT for the drug (X) over a 15-year period?

Answer → 30

N.B. The **lower** the NNT the **better** the drug.

*If you do not understand the following equations, leave them for now as they will be explained with examples later in this chapter.*

- AR (absolute risk) = the number of events (good or bad) in treated or control groups, divided by the number of people in that group.

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- ARC = the AR of events in the **C**ontrol group
- ART = the AR of events in the **T**reatment group
- ARR (absolute risk reduction) = ARC – ART
- RR (relative risk) = ART / ARC
- RRR (relative risk reduction) = (ARC – ART) / ARC
  RRR = 1 – RR
- NNT (number needed to treat) = 1 / ARR

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## Example (2)

The **control** group has death in 20% of the patients, and the **treatment** group has deaths in 10% of the patients.

- What is the Absolute risk reduction (**ARR**)?
- How many patients would you have to treat to prevent one death (What is the Needed Number to Treat **NNT**)?

Answer:

- **ARR** = ARC – ART = 20 – 10 = **10**%
- **NNT** = 1 ÷ ARR = 1 ÷ (10%) = **10**

*10% = 10 ÷ 100 = 0.1*

*1 ÷ 0.1 = 10*

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## Example (3)

A randomised control trial is conducted to assess new treatment for COVID 19. In the control group, 60 out of 100 patients developed severe complications. On the other hand, in the treatment group only 10 out of 100 patients developed severe complications. What is the number needed to treat (NNT) for this new drug?

Answer:

√ NNT = 1 / ARR (absolute risk reduction).

√ ARR = ARC (absolute risk in the control group) – ART (absolute risk in the treatment group).

√ ARC = 60/100 = 0.6

√ ART = 10/100 = 0.1

√ ARR = 0.6 – 0.1 = 0.5

NNT = 1 / 0.5

NNT = 2.

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## Example (4)

A randomized controlled trial investigates the efficacy of a new drug for reducing the incidence of acute exacerbations in patients with chronic obstructive pulmonary disease (COPD). In the study, 2000 patients are randomly assigned to either the new drug or a placebo. The results after one year show that 120 out of 1000 patients in the drug group experience at least one exacerbation, compared to 220 out of 1000 in the placebo group.

What is the number needed to treat (NNT) to prevent one patient from having an exacerbation?

√ NNT = 1 / ARR (absolute risk reduction).

√ ARR = ARC (absolute risk in the control group) – ART (absolute risk in the treatment group).

√ ARC = 220/100 = 0.22

√ ART = 10/100 = 0.12

√ ARR = 0.22 – 0.12 = 0.10

NNT = 1 / 0.10

√ NNT = 10.

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**Key 2**

## Standard Deviation (SD)

- **Definition**: *The measure of Dispersion (Spread) of a set of Values (Observations)*. (Important!)

- Remember these numbers:
- **1SD** is 68.2
- **2SD** is 95.4
- **3SD** is 99.7

- Measures of **Central Tendency** → Mean, Median, Mode
- Measures of **Dispersion** → Standard Deviation, Standard error of mean.

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**Key 3**

## Sensitivity and Specificity Calculations

- **Sensitivity** = True Positive ÷ (True Positive + False Negative)
- **Specificity** = True Negative ÷ (True Negative + False Positive)

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| | Disorder | No Disorder |
|---|---|---|
| Positive Test Result | True Positive (TP) | False Positive (FP) |
| Negative Test Result | False Negative (FN) | True Negative (TN) |

Sensitivity = TP/(TP+FN)
Specificity = TN/(TN+FP)
PPV = TP/(TP+FP)
NPV = TN/(FN+TN)

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| Symptom/Characteristic/Case Definition | | + | - |
|---|---|---|---|
| | + | A True Positives | B False Positives |
| | - | C False Negatives | D True Negatives |

Sensitivity = A/(A+C)

Specificity = D/(D+B)

Positive Predictive Value = A/(A+B)

Negative Predictive Value = D/(C+D)

Accuracy = (A+D) ÷ (A+B+C+D)

**SenSitivity** truly detects those who are **S**ick.

**SpeciFicity** truly detects those who are **F**it.

**PPV** → The percentage of **Positives** that are **true Positives**.

**NPV** → The percentage of **Negatives** that are **true Negatives**.

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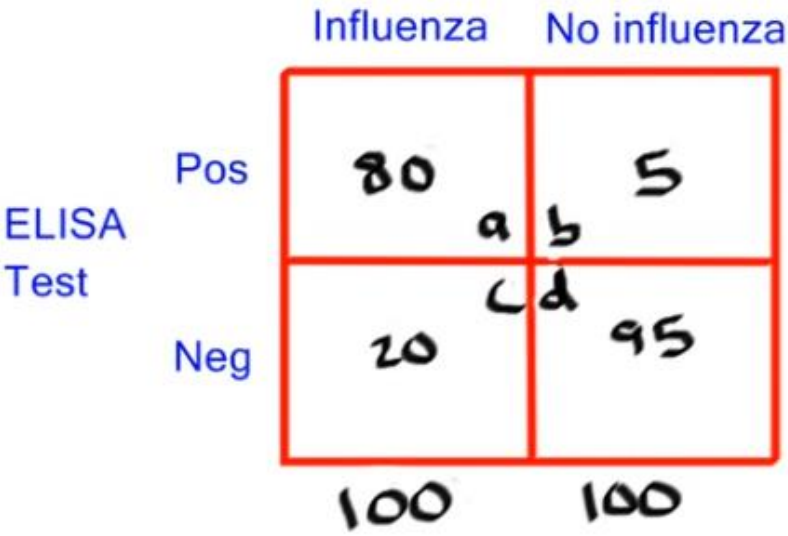
# Example

200 patient are enrolled in a study to evaluate the accuracy of a new ELISA-based test for influenza.
100 of the patients were diagnosed with influenza by the reference standard culture of respiratory secretions.
80 of the patients with influenza had a positive ELISA-based test as did 5 of the patients without influenza.
What is the sensitivity of the ELISA-based test?




*** Sensitivity = a ÷ (a+c) = 80 ÷ 100 = 80%**

*** Specificity = d ÷ (d+b) = 95 ÷ 100 = 95%**

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**Key 4**

# Absolute Risk (AR)

The percentage of people among a certain group who got an event (e.g., death, disease).

**AR** = **The number of events ÷ The total number of populations within that group.**

## Example (1)

We have 200 patients, 10 of them died while on drug A, 20 of them died while on drug B. What is the Absolute Risk (AR) for the patients on drug **B**? and what is the Absolute Risk for the patients on drug **A**?

Answer:

**The AR for drug B**

**20** of **200** on drug **B** died

➔ AR = 20 ÷ 200

➔ = 0.1

➔ To convert to **%** ➔ 0.1 X **100**

➔ = **10%**

**The AR for drug A**

**10** of **200** on drug **A** died

➔ AR = 10 ÷ 200

➔ = 0.05

➔ To convert it to % ➔ 0.05 X 100

➔ = **5%**

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## Example (2)

A study on MI shows that 10 patients out of 100 died who did not get treatment and 10 out of 100 died who received proper treatment. What is the AR (Absolute Risk) for the patients who got proper treatment?

**AR** = the number of events (deaths here) ÷ the number of populations in his group

= 10 ÷ 100

= 0.1

To convert it into a percentage, multiply it by 100

→ **10%**

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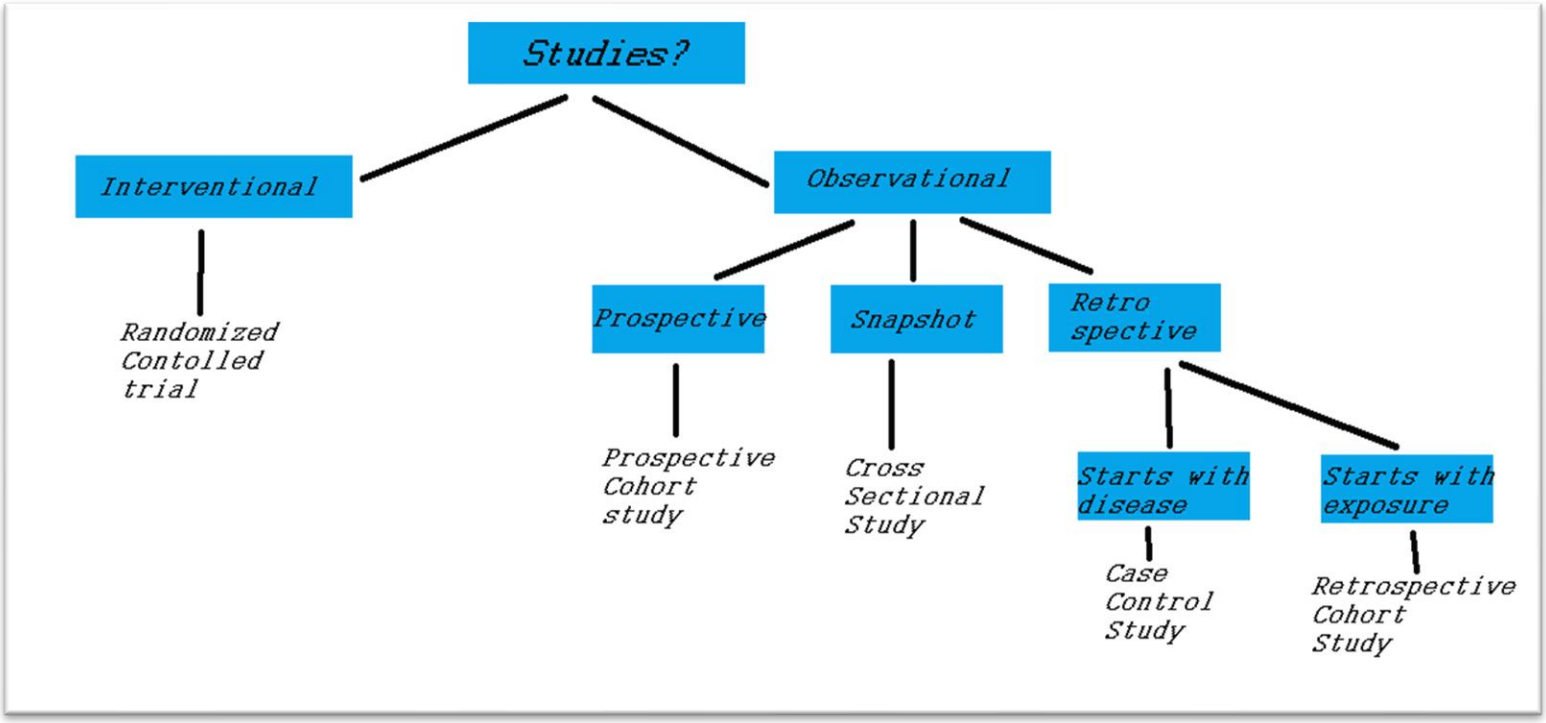
**Key 5**

# Case-Control VS Cohort Studies




**Case contol study** — **Effect (Outcome)** → **Cause (Exposure)**

**Retrospective cohort study** — **Cause (Exposure)** → **Effect (Outcome)**

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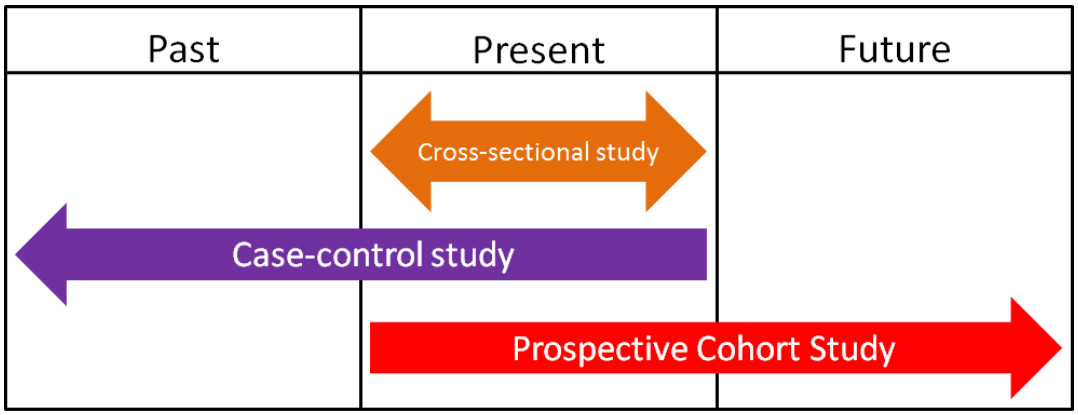
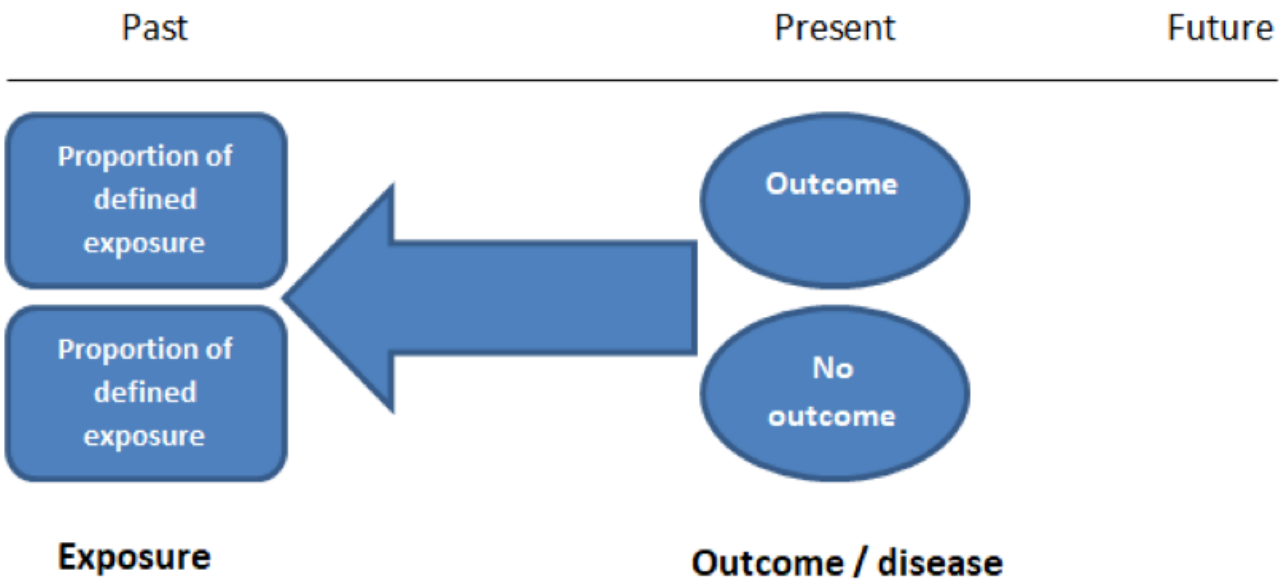



## Case-control studies

Case-control studies are **retrospective**. They clearly define two groups at the start: one with the outcome/***disease*** and one without the outcome/disease (**starts with the disease**)

They **look back** to assess whether there is a statistically significant difference in the rates of exposure to a defined risk factor between the groups.

The main outcome measure in case-control studies is **odds ratio (OR)**.

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*Case-control studies should include two groups that are identical EXCEPT for their outcome / disease status.*

As case-controls are **retrospective**, they are more prone to **bias**. One of the main examples is **recall bias**.

| Case-control studies | |
|---|---|
| **Advantages** | **Disadvantages** |
| Cheaper | Retrospective / more prone to bias |
| Quicker / easier to conduct | Can only assess one outcome / disease |
| Good for diseases with long latency periods | Cannot establish risk |
| Can assess multiple exposures | Cannot establish prevalence |
| Good for rare diseases | |

## Cohort studies

Cohort studies can be **retrospective** or **prospective**. Retrospective cohort studies are NOT the same as case-control studies which are retrospective as well.

In **Retrospective cohort studies**, the **exposure** and **outcomes** have **already happened**. They are usually conducted on data that already exists (from prospective studies) and **the exposures are defined before looking at the existing outcome** (**starts with exposure**) data to see whether exposure to a risk factor is associated with a statistically significant difference in the outcome development rate.

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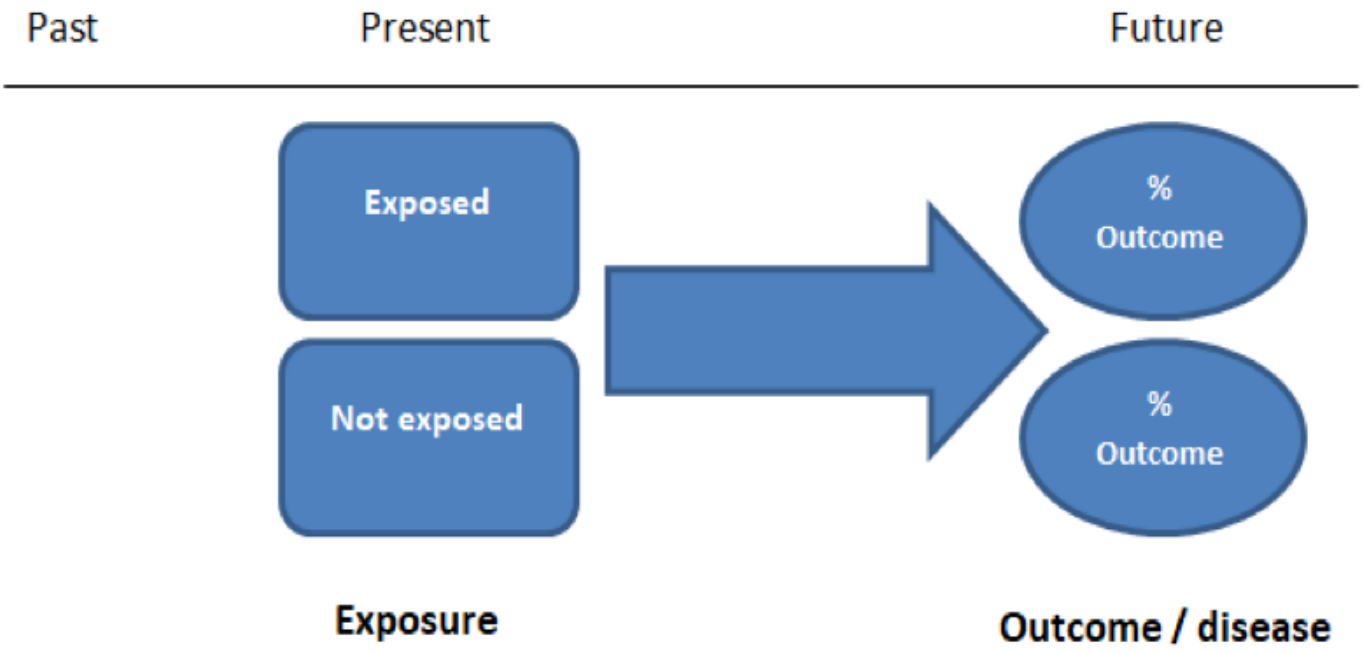
**Prospective cohort studies** are more common. People are recruited into cohort studies regardless of their exposure or outcome status. Researchers can then measure and analyse a range of exposures and outcomes.

***The study then follows these participants for a defined period to assess the proportion that develop the outcome/disease of interest***.

cohort studies are good for assessing prognosis, risk factors and harm.

The outcome measure in cohort studies is usually a risk ratio / relative risk (RR).

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| Cohort studies | |
|---|---|
| **Advantages** | **Disadvantages** |
| Prospective (usually) | More expensive |
| Can establish risk directly | Longer / harder to conduct |
| Can assess multiple outcomes / diseases | Not good for rare diseases |
| Good for rare exposures | Not good for diseases with long latency periods |

## In Short:

• **In case-control** (Retrospective only), one **starts from the outcomes** i.e., cases and bases/controls/referents (matched or not) and **tries to study what the exposure was**. As case-controls are **retrospective only**, they are more prone to **bias**. One of the main examples is **recall bias**.

• **Retrospective cohort** is when **one already has determined the exposure in the study cohort and tries to study the association of exposure to disease** outcome within that cohort in a retrospective manner.

• In **Prospective cohort**, we follow the groups **from the scratch** overtime and see what are the exposures and the outcomes.

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All these three studies (Retrospective Case-Control ▌Retrospective Cohort ▌Prospective cohort) are OBSERVATIONAL, we do not intervene, we don't give incentives, or add any measures or drugs during the study! Take care that researchers may follow 2 different groups who have already received 2 different drugs/ vaccines. This is still observational as the researchers did not offer these measures or intervene.

√ On the other hand, in

(experimental/interventional trials,

ie, randomised or non-randomised controlled study,

one group will be taking a drug, the other will be taking a placebo or a different drug. These drugs are offered by the study makers (researchers) to see their effects on the groups with time. This is an intervention not just an observation. So, this is a randomised control study.

Another important example of experimental studies (controlled trials) is to give one group incentives (eg, financial rewards) to make them use drug A, while group B is not receiving any incentives. This is an assigned intervention/ exposure. Therefore, this is an experimental (randomised/non-randomised controlled trial), not an observational study (cohort, case-control, cross-sectional).

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**Example (1)**

2 groups - free of disease - are followed over 10 years to see exposure to certain factors would cause pulmonary diseases or not.

*The type of study* ➔ ***Prospective Cohort Study***.

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**Example (2)**

2 groups have already received 2 different types of vaccines (vaccine A and vaccine B) for COVID19. The researchers did not choose who receive which type of vaccine. Anyway, both groups were then followed in time to see who would develop COVID19.

*The type of study* ➔ ***Prospective Cohort Study***.

*(Still considered **observational** as the researchers did not intervene and give drugs or choose the vaccine types).*

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**Example (3)**

2 groups of smokers are followed over time. One group will be taking drug (A), while the other group will be taking Placebo. They are then followed over time to see who would develop lung cancer.

As drug A and placebo are offered by the study makers (assigned intervention)

→ ***Randomised control trial***. (Interventional).

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## Example (4)

2 groups of schizophrenic patients were tested for adherence to a new medication. Patients in group A were receiving financial incentives to encourage them take the new drug while those in group B were not receiving any incentives. The study showed more adherence to medication in group A. What is the type of study?

Since there is an assigned intervention/ exposure (financial incentives here)

→ This is an **experimental/ interventional study**, not an observational one.

It could be a (**randomised**, or **non-randomised controlled trial**).

---

## Example (5)

In an **observational** study, 2 groups of patients with chronic migraine were examined. One group was given drug (A), the other group was given drug (B). They then were followed for 5 years to measure and compare the frequency and severity of migraine between the 2 groups. What is the type of this study?

Since the groups were given measures and then followed in time to see the effects:

→ This is a **prospective cohort study.**

**Why not randomised control trial?**

→ The stem mentions that it is an "observational study". Randomised control trials are not observational but experimental studies.

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# Key 6

## Randomised Control Trial (Interventional)

One group is taken a drug, the other is not. Then both groups are followed over time to see the outcome. The drugs are offered by the researchers to see their effects on the groups.

**The Key is the introduction of an intervention (e.g. a drug).**

### Example

2 groups of smokers are followed over time. One group **will be taking drug (A)**, while the other group will be taking Placebo. They are then followed over time to see who would develop lung cancer. Drug A and placebo are offered by the study makers.

⇨ **Randomised control trial**. (Interventional)

*Remember, in **Prospective cohort studies**, we do not intervene by giving any drugs. We **only Observe** the Risk Factors and look for the outcome over a period of time.*

*Very Important: If the drugs were not offered by the researchers, but the participants are already being taking these drugs and the researchers only observe with time the effect of these drugs, this is called "prospective cohort study". Both scenarios had been asked previously so careful! (See key 38).*

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**Key 7**

## Sensitivity VS Specificity in a Test

| | |
|---|---|
| High SeNsitivity test | Few **False** Negatives |
| Low SeNsitivity test | Many **False** Negatives |
| High SPecificity | Few **False** Positives |
| Low SPecificity | Many **False** Positives |

**How to memorise it?**

- The word "**False**" is constant in all conditions.
- With "High" ➔ Few.
- With "Low" ➔ Many.
- SeNsitivity ➔ Look for Negatives.
- SPecificity ➔ Look for Positives.

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## Example (1)

A new test (AD test) to diagnose Addison's disease is being tried on 1000 patients. 900 of them show positive (AD test). Only 100 of these 900 are diagnosed with Addison's disease.

**High False Positives ➔ Low Specificity.**

## Example (2)

A new test called (LNC9) is being tested on 10,000 people to diagnose Lung cancer. 700 of these show Positive LNC9. Out of these, 670 were Positive on lung biopsy.

**Few False Positive (Only 30 are false positives) ➔ High Specificity.**

## Example (3)

A new test called (BrC10) is tested on 10,000 women to detect breast cancer. 8000 of these showed Negative BrC10. 7800 were truly negatives on breast biopsy.

**Few False Negative (Only 200 of the 8000 were False negatives)**

**➔ High Sensitivity Test.**

---

**Key 8**

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# The Relative Risk (RR)

| | |
|---|---|
| **Relative Risk (RR)** | Incidence rate in Exposed ÷ Non-exposed (OR)<br>**(AR** Test -treatment- **group ÷ AR** Control **group)** |

**RR Relative Risk** = **(Incidence rate in the exposed group (smokers)) / (Incidence rate in the unexposed group (non-smokers))**

## Example (1)

A study examines the effect of smoking on developing Lung Cancer over a period of 10 years. 400 people were involved. 200 are smokers and 200 are non-smokers. 10 of the 200 smokers developed lung cancer. 2 of the non-smokers developed lung cancer. What is the Relative Risk of developing lung cancer in the smoking group?

**RR Relative Risk** = **(Incidence rate in the exposed group (smokers)) / (Incidence rate in the unexposed group (non-smokers))**

**Incidence rate in smokers (Exposed) = 10 ÷ 200 = 0.05**

**Incidence rate in Non-Smokers (Non-Exposed) = 2 ÷ 200 = 0.01**

**RR = 0.05 ÷ 0.01 = 5**

**This means that smoking increases the risk of Lung cancer by 5 Folds.**

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## Key 9

## Repeated: on Sensitivity VS Specificity

### Example

A new screening test is designed to detect the early stages of prostate cancer. The test showed a high number of positive results. However, another definitive test confirms that only a few of these were truly positives.

**High False Positive rate ➔ Low Specificity**

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## Key 10

## False Negative

### Example

1000 men had a newly designed test for prostate cancer. 100 of them were found to have prostate cancer. Out of the remaining negative 900, 8 were diagnosed later by a definitive test and found to have prostate cancer. What can we call these 8?

⇨ **False Negative.**

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*As they were among the negative results but later found to be positive by a definitive diagnostic test. So, they are False Negative.*

---

**Key 11**

## Incidence and Prevalence

| | |
|---|---|
| **Incidence** | Number of **NEW** cases / populations at risk |
| **Prevalence** | Number of **NEW** + **OLD** cases / population at risk |

### Example (1):

A town has a population of **500,000** people. Over **5** years, 1250 cases were diagnosed with COPD. In the same town, another 500 people were diagnosed with COPD by another health institution.

What is the ***annual Prevalence and Incidence*** for COPD ***per million*** in this town?

### Answer:

Pay attention to the last line of the question.

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- It asks about the prevalence (**per million**), whereas the question gives you **half a million** (**500,000 people**). Therefore, ***we need to multiply our result by 2 to convert it to a million***.
- Also, it asks about the **annual** (**one year**), while the question gives you (**5 years**); thus, ***we need to divide our result later by 5***.

Prevalence = (New cases + Old case) / Population at risk

= 1250 + 500 ➔ 1750

X 2 ➔ 3500

÷ 5 ➔ **700 (The annual prevalence per million)**

Incidence = New cases / Population at risk

= 500 (The newly diagnosed patients)

X 2 ➔ 1000

÷ 5 ➔ **200 (The annual incidence per million)**

## Example (2):

A city has **250,000** people. 1000 were diagnosed with lung cancer by the governmental health sector over **a 3-year period**. Another 500 were diagnosed with lung cancer by the private sector over the same period. What is the **annual** Prevalence **per million** in this population?

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**Answer:**

**Prevalence = Old cases + New cases / Population at risk**

= 1000 + 500 ➔ **1500**

The population is 250,000. To convert it to a million (as required in the question), we need to multiply it by 4

1500 X 4 ➔ **6000**

This is for the period of 3 years. To convert it to one year (as the question asks about the **annual** prevalence), we need to divide it by 3.

6000 ÷ 3 ➔ **2000** (**The annual Prevalence per Million**).

## Example (3):

A city has **20,000** people. 1000 were tested randomly for Type 2 diabetes. Out of these 1000 people, 150 were diagnosed with types 2 diabetes mellitus. What is the estimated prevalence of Types 2 diabetes in this town **per 100,000 residents**?

**Answer:**

**Prevalence = Old cases + New cases / Population at risk**

√ 150 (total cases here) ÷ 1000 (the population at risk, ie, there who were tested).

= 0.15 *(This is the prevalence per 1000).*

√ To convert it into a percentage, multiply it by 100:

0.15 × 100 = 15%.

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√ To find the prevalence per 100,000 people:

15% × 100,000

= 0.15 × 100,000

= 15000 *(This is the prevalence per 100,000).*

---

**Key 12**

## Sensitivity and Specificity definitions

- **Sensitivity** identifies those who are truly **S**ick.
- **SpeciFicity** identifies those who are truly **F**it (well).

- **Sensitivity** ➔ ***The likelihood of a test reporting positive when the condition being tested is actually present.***

**Also**

Sensitivity → Positive predictive value.

Specificity → Negative predictive value.

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**Also**

Low sensitivity → many false negatives.

High sensitivity → few false negatives.

Low specificity → many false positives.

High specificity → few false positives.

---

**Key 13**

## Common Causes for a dropout from a study

**Example**

A double-blind study was performed on 2 groups of patients over a year. One group was receiving an active drug while the other group was receiving a placebo. After 6 months, 27% of the placebo group dropped out of the study while 4% of the active group dropped out. What is the most likely cause for this?

→ **Breakdown of the double-blind study**.

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Another valid answer → **The groups in the blinded trial were accidentally revealed to the researchers**.

## Explanation:

We can see that a massive percentage of the placebo group had dropped out (27%) compared to a small percentage of the active drug group (only 4%). This might indicate that the **placebo group had figured out** that they are not taking a real active drug and thus dropped out of the study in large numbers. This is called (Breakdown of the double-blind study).

*They have figured out that they are being used and deceived, so they have decided to BREAK the whole study as 27% of those being deluded with Placebo had left :D*

**Important**, if the percentages of the dropout were small in both groups (below 15% for instance), this could be due to a **Chance event**. A chance event can happen due to any cause such as loss of follow up, death, travelling. It should be a small percentage to be considered as a **Chance Event**.

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# Key 14

## Relative Risk Reduction (RRR)

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| | |
|---|---|
| **Relative Risk Reduction (RRR)** | **1 – RR (Relative Risk) OR:**<br>**(ARC – ART) / ARC** |

- ARC: Absolute Risk Reduction in the Control group" Placebo group".
- ART: Absolute Risk Reduction in the Test group (**T**reatment = Exposure) group.

## Example 1

| | Number of patients who developed lung cancer over 5 years | Number of patients who did not develop lung cancer over 5 years |
|---|---|---|
| Using Lun9 drug | 4 | 96 |
| Using Placebo | 10 | 90 |

**Calculate the RRR.**

**ARC** (**C**ontrol = Placebo) ➔ 10 / (10+90) ➔ 10/100 ➔ 0.1

**ART** (**T**reatment group) ➔ 4 / (4+96) ➔ 4/100 ➔ 0.04

**RRR** = (ARC-ART) ÷ ARC ➔ (0.1 – 0.04) ÷ 0.1 = **0.6**

(Multiply it by 100 to convert it to a percentage) ➔ **60%**

---

## Example 2

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A new MI protective drug is being used on **100** patients who have many Risk Factors for MI, while a placebo was used for another **100** patients. After a 5-year period, **7** of the active treatment group had developed MI while **20** of the placebo group had developed MI. What is the Relative Risk Reduction**?**

**RRR = (ARC – ART) ÷ ARC**

ARC (control=placebo group) = 20/100 = 0.2

ART (Treatment group) = 7/100 = 0.07

RRR = (0.2 – 0.07) ÷ 0.2 = 0.65

0.65 X 100 = 65% **(**Multiply it by 100 to get the percentage %**)**

---

## Example 3

2 groups of smokers. Group A was given a new medication (LCP10) to protect from lung cancer. Group B was given a placebo. They were then followed over 10 years. These are the results:

| | Number of smokers who developed lung cancer over 10 years | Number of smokers who did not develop lung cancer over 10 years | Total |
|---|---|---|---|
| Using LCP10 drug | **20** | **80** | **100** |
| Using Placebo | **40** | **60** | **100** |

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What is the **relative risk reduction**?

| **Relative Risk Reduction (RRR)** | **1 – RR (Relative Risk) OR:**<br>**(ARC – ART) / ARC** |
|---|---|

- ARC: Absolute Risk Reduction in the Control group" Placebo group".
- ART: Absolute Risk Reduction in the Test group (**T**reatment = Exposure) group.

So, we first need to calculate Absolute Risk in both groups (ARC and ART).

**AR** = **The number of events ÷ The total number of populations within that group.**

**ARC** (**C**ontrol = Placebo) → 40 / 100 = **0.4**

**ART** (**T**reatment group) → 20 / 100 = **0.2**

Now, we have **ARC** and **ART**:

**RRR** = (ARC-ART) ÷ ARC

(0.4 – 0.2) ÷ 0.4

= 0.2 ÷ 0.4

= 0.5

(Multiply it by 100 to convert it to a percentage) → **50%**

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**Key 15**

# Absolute Risk Reduction (ARR)

| | |
|---|---|
| **Absolute Risk Reduction (ARR)** | **AR Control** (Placebo) **group - AR Test** (Treatment) **group**<br>**i.e. Absolute Risk in Control group – Absolute Risk in Treatment group** |

**In short**

**ARR = ARC – ART**

**RRR = (ARC – ART) ÷ ARC**

## Example (1)

A new MI protective drug is being used on **100** patients who have many Risk Factors for MI, while a placebo was used in another **100** patients. After a 5-year period, **7** of the active treatment group had developed MI while **20** of the placebo group had developed MI. What is the Absolute Risk Reduction (ARR)**?**

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**ARR = ARC – ART**

- ARC "Control=Placebo" = 20/100 = 0.2
- ART "Treatment group" = 7/100 = 0.07
- ARR = 0.2 – 0.07 = 0.13
- To convert it to % ➔ 0.13 X 100 = 13%

---

## Example (2)

A study on a new drug to reduce the risk of Heart failure was conducted over a 5-year period with the following results:

100 out of 1000 patients on **Placebo** drug developed HF in 5 years.

50 out of 1000 patients on the **new drug** developed HF in 5 years.

What is the **Absolute Risk Reduction** (**ARR**)?

What is the **Relative Risk Reduction** (**RRR**)?

**ARR = ARC – ARC**

ARC (Absolute Risk of Control "Placebo" group) = 100/1000 = 0.1

ARC (Absolute Risk of Treatment group) = 50/1000 = 0.05

ARR = 0.1 – 0.05 = **0.05**

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To convert it to a percentage ➔ 0.05 X 100 = **5%**

**RRR = (ARC – ART) ÷ ARC**

**ARC = 100/1000 = 0.1**

**ART = 50/1000 = 0.05**

**RRR = (0.1 – 0.05) ÷ 0.1**

**= 0.05 ÷ 0.1**

**= 0.5**

**To convert it to % ➔ 0.5 X 100 = 50%**

---

# Key 16

## Relative Risk (RR)

**RR = Exposed ÷ Non-exposed (OR)** (AR **Treatment** group ÷ AR **Control** group)

### Example

A study was conducted to evaluate the risk of developing COPD in smokers over a 5-year period. Group A who did not receive any drug contained 100 people, 4 of them developed COPD. Group B who was given a trial drug contained 100 people, 3 of them developed COPD. What is the **Relative Risk (RR)?**

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**RR = ART (Treatment group) ÷ ARC (Control group)** **"Be careful, ÷ NOT –"**

**= 3 ÷ 4**

**= 0.75**

**= 75% (Multiply it by 100 to get %)**

---

# Key 17

## Median definition

**The value of observation that comes halfway when observations are ranked in order. It is particularly important if the distributions are not normal.**

---

# Key 18

## Incidence

**Incidence is the number of the new cases among a population during a specific time.**

### Example

**50,000 cases of prostate cancer are diagnosed yearly in a population of 90,000,000. Out of these, 20,000 died in the first 5 years and 30,000 live. What is the incidence of prostate cancer?**

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**Incidence = the New Cases in the population at risk**

**= 50,000 in 90,000,000**

---

**Key 19**

# Incidence

## Example

Town **A** has 250,000 people and there are 1000 cases of liver cancer diagnosed every 5 years. Town **B** also has 250,000 people and there are 400 cases of liver cancer per 5 year. What is the **annual** incidence of liver cancer in both town **per million**?

- The question asks about "both towns"; thus, we have to add the new cases of the two towns (**1000+400 = 1400**).
- The total population of the two towns = 250,000+250,000 = half a million (500,000). In order to get a "**million**" as required in the question, we need to multiply it and multiply the above result by 2. So, (**1400 X 2 = 2800)**.
- The final step is the year. The question asks about the "**annual**" incidence whereas the number of cases given in 5 years. Therefore, we need to divide our result by 5 to get it converted to one year as required in the question. So, (**2800 ÷ 5 = 560**)

**1000 + 400 = 1400**

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**1400 X 2 = 2800**

**2800 ÷ 5 = 560**

---

# Key 20

## Randomised Control Trial (Interventional)

This kind of study has an **Intervention** = we use an intervention to see its effect on a particular disease or outcome. Examples of interventions include ***drugs***, ***procedures***, ***techniques***…etc. The groups are then followed in time and their outcomes are recorded.

### It has two types:

- **Single-Blinded** (where either the researchers **or** the candidates do not know who's using the real treatment and who's receiving a placebo. Only one of them is blind to this information: the researchers or the recruited candidates.
- **Double- Blinded** (Where BOTH the researchers and the candidates are blind to this information).

### Example (1)

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Two groups of children were followed up in time to see the effect of adding a new mineral to the drinking water and its relation to developing cholera. One group has this mineral in their water while the other did not have it. The researchers did not know which group of candidates had used the mineral. **What is the study type**?

As there is an intervention (Adding a mineral into water)

➔ **Randomised Control Trial**

As one party (the researchers) were blinded ➔

**Single-Blinded Randomised Control Trial**.

If both the researchers and the candidates did not know who is using the new mineral ➔ **Double**-Blinded Randomised Control Trial.

## Example (2)

A research group evaluates the effect of financial incentives on treatment adherence in patients with schizophrenia. They enrol 300 patients who are receiving care from several mental health clinics across a metropolitan area. Each clinic is randomly allocated to either the intervention arm, where patients receive a monetary bonus for adhering to their antipsychotic treatment, or the control arm, where patients receive standard care without financial incentives. The study's primary outcome is the adherence to antipsychotic medication measured over a 12-month period. Which type of study design does this scenario best illustrate?

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A) Cohort study.

B) Cluster-randomised controlled trial.

C) Cost benefit analysis.

D) Cross-sectional study.

E) Cost utility analysis.

**Answer → B.**

Cluster-randomised controlled trial. This is because the random allocation to intervention and control groups occurs at the level of the clinics (clusters), rather than individual patients.

*Key Question to Determine Study Design*:

**Did the investigator assign an exposure?**

• Yes → It's an experimental (interventional) study, which could be a randomized or non-randomized controlled trial.

• No → It's an observational study, which could be a cohort study, case-control study, or cross-sectional study.

**Cluster-randomized Controlled Trials (CRTs):**

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- Randomization occurs at the level of clusters (e.g., clinics), not individual patients.

- Each clinic is allocated to either the intervention or control arm.

- Used when individual randomization is impractical or when interventions are delivered on a group basis.

---

## Key 21

## Description

A new Screening Test called **BRT-23** was conducted on a number of Females with high risk of developing breast cancer. **Breast biopsy** was then performed to either confirm or exclude the results. **80** of the candidates were shown positive on both tests (BRT-23 and Breast biopsy), **40** were diagnosed as having breast cancer by BRT-23 but were free on breast biopsy, **8** were negative by BRT-23 but Positive on breast biopsy, and finally **240** candidates were negative on both tests.

**What is the best description for the 40 candidates?**

**Answer:**

- 80 → +ve in both tests. → **True Positive**.
- 40 → +ve on BRT-23 but -ve on Biopsy. → **False Positive**.

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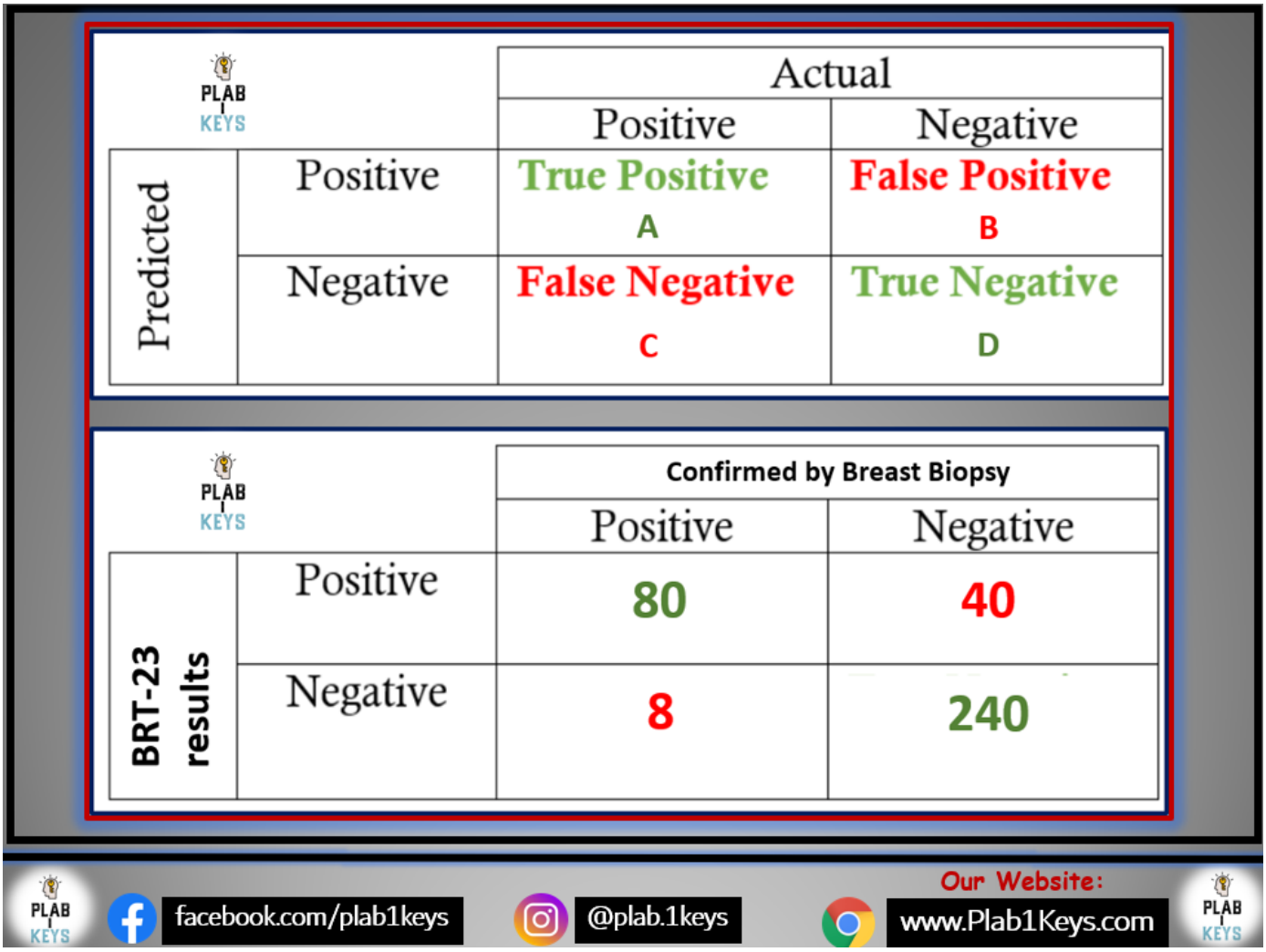
- 8 → -ve on BRT-23 but +ve on Biopsy. → **False Negative**.
- 240 → -ve on both tests. → **True Negative**.

So, the right answer is that the 40 cases are described as:

→ **False Positive** (See the picture below)

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## Key 22

**If you know that 15 out of 100 who truly have prostate cancer will have normal Prostate Specific Antigen (PSA). And,**

**2 out of 3 who with high PSA will not have prostate cancer on biopsy.**

**The False Positive rate** = 2/3 = 0.6 → (X 100) → 66.6%

**(2 people out of 3 do not truly have prostate cancer although their PSA is high**

**→ It is falsely high**!)

---

## Key 23

**30 patients needed to use drug (X) to prevent lung cancer compared to a placebo drug. This study is continued for 15 years. What is the NNT (the number needed to treat) for the drug (X) over a 15-year period?**

Answer → **30**

NNT = **one patient benefit**

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## Key 24

**A study showed that 29 patients with Hx of MI needed to be treated with Aspirin to prevent 1 MI. The 95% confidence interval is (20, 38). What it is the interpretation of this data?**

→ **The number of patients that need to be treated with aspirin to prevent 1 MI is likely between 20 to 38.**

## Key 25

**To test the efficacy of a new medication in preventing a cardiovascular event, a study was conducted. 100 people received placebo. Another 100 people received the new medication. All-cause mortality was 34% for the true treatment group, and 40% for the placebo (control) group. What is the number need to treat (NNT)?**

◙ **NNT** = 1 ÷ Absolute Risk Reduction (ARR)

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◙ **ARR** = AR **C**ontrol (Placebo) group – AR Test (**T**reatment) group

(AR**C** – AR**T**)

= 40% – 34%

= 0.40 – 0.34

**So,**

→ **NNT = 1 ÷ (0.40 – 0.34)**

- **The NNT is the average number of patients who need to be treated to prevent one additional bad outcome (e.g. the number of patients that need to be treated for one of them to benefit compared with a control in a clinical trial).**
- **It is defined as the inverse of the absolute risk reduction (ARR)**

**i.e. NNT = 1/ARR**

---

## Key 26

**10000 women were screened using a new cervical cancer screening method. 1000 were shown to have changes, 100 were positive after biopsy. Another 10 not picked initially by the new test went on to develop cervical CA. What term describe the 900 out of the 1000 who were negative on biopsy.**

A. Incidence

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B. **False positive**

C. False negative

D. True positive

E. True negative

**The new test showed 1000 woman with POSITIVE results. However, only 100 of these 1000 were truly POSITIVE on the biopsy. This means that the remaining 900 were FALSE POSITIVE.**

---

## Key 27

### What is the best description?

**Q1)** 8000 people were screened for skin cancer using a new screening tool. The new test shows 600 suspicious cases. Out of these 600, only 100 were positive by skin biopsy. What is the best description for the negative 500?

Answer → False Positive

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600 were positive on the new test but only 100 were truly positive on biopsy.

This means that the 500 are falsely positive

i.e. (they appeared positive on the new test but in fact they are not positive as confirmed by skin biopsy).

---

**Q2)** A new Screening Test called **BRT-23** was conducted on a number of Females with high risk of developing breast cancer. **Breast biopsy** was then performed to either confirm or exclude the results. **80** of the candidates were shown positive on both tests (BRT-23 and Breast biopsy), **40** were diagnosed as having breast cancer by BRT-23 but were free on breast biopsy, **8** were negative by BRT-23 but Positive on breast biopsy, and finally **240** candidates were negative on both tests.

**What is the best description for the 8 candidates?**

Answer → False Negative

These 8 cases were negative on the test.

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However, on biopsy, they turned to be positive.

Thus, they are falsely negative.

---

## Key 28

### Mean vs Median vs Mode

- **Mean** → Sum of values divided by their number.

- **Median** → The middle value of arranged list of numbers "arranged from the smallest to the biggest"

Note: (if the number of values is an even number, take the mean of the middle 2 numbers).

♦ **Important definition for Median for the exam:**

"Half of a group of observations lies above the level of the median; it is particularly important if the distributions are not normal".

- **Mode** → The value that was repeated the most.

Now, we have the following 2 examples:

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## Example (1):

**Calculate the mean, median and mode for the following set of values:**

**40, 10, 20, 30, 40**

The answer:

- **Mean**: (40+10+20+30+40) ÷ 5 = **28**
- **Median**: we need to re-arrange the values as follows:

10, 20, 30, 40, 40

The median "the middle value" here is **30**.

- **Mode** → **40** (repeated the most).

---

## Example (2):

**Calculate the mean, median and mode for the following set of values:**

**5, 10, 15, 20, 25, 30**

The answer:

- **Mean**: (5+10+15+20+25+30) ÷ 6 = (105 ÷ 6) = **17.5**

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• **Median**: the values are already arranged. However, the number of the values is 6; which is an even number. Thus, we need to take the mean of the middle 2 numbers (the middle 2 numbers ÷ 2)

→ (15+20) ÷ 2 = 35 ÷ 2 = **17.5**

• **Mode** → **Invalid** (No value has been repeated within this set of values).

---

**Key 29**

## Secondary Attack Rate

**2ry attack rate** =

number of 2ry cases ÷ (All people in the group – number of the 1ry cases)

**Example**:

A new virus has infected 10 people out of 40 bus riders during a long trip. These infected 10 people had transmitted the virus to additional 50 relatives. The total number of the relatives including the 10 infected people is 110. What is the 2ry attack rate?

number of 2ry cases = 50

All people in the group = 110

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number of the 1ry cases = 10

2ry attack rate = 50 ÷ (110 – 10)

= 50 ÷ 100

= 0.5 (X 100 → 50%)

**1ry attack rate** =

(Number of 1ry cases ÷ total population at risk) X 100

**So, in the example above:**

Number of 1ry cases = 10

Total pop at risk (bus riders) = 40

(10 ÷ 40) X 100

= 25%

---

## Key 30

To measure the accuracy of a screening test:

**Accuracy = a+d ÷ (a+b+c+d)**

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| | + | - |
|---|---|---|
| + | A True Positives | B False Positives |
| - | C False Negatives | D True Negatives |

---

## Key 31

## Control Trial (**Interventional**)

One group is taken a drug, the other is taken another drug. Then both groups are followed over time to see the outcome.

**The Key is the introduction of an intervention (e.g. a drug).**

### Example

2 groups of smokers are followed over time. One group **is taking drug (A)**, and the other group is taking drug (B). They are then followed over time to see who would develop lung cancer. What is the type of the study?

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- ⇨ **Control trial**. (Interventional)

Remember, in case-control and cohort studies, no interventions (only observational).

---

**Key 32**

## Common Causes for a dropout from a study

### Example

A double-blind study was performed on 2 groups of patients over a year. One group was receiving an active drug while the other group was receiving a placebo. After 6 months, 27% of the placebo group dropped out of the study while 4% of the active group dropped out. What is the most likely cause for this?

- ⇨ **Breakdown of the double-blind study**
- ⇨ **Another valid answer → The groups in the blinded trial were accidentally revealed to the researchers.**

### Explanation:

We can see that a massive percentage of the placebo group had dropped out (27%) compared to a small percentage of the active drug group (only 4%). This might indicate that the **placebo group had figured out** that they are not taking a real

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active drug and thus dropped out of the study in large numbers. This is called (Breakdown of the double-blind study).

**If the researchers discover the active an the placebo groups, they may start to treat patients differently.**

*They have figured out that they are being used and deceived, so they have decided to BREAK the whole study as 27% of those being deluded with Placebo had left :D*

**Important**, if the percentages of the dropout were small in both groups (below 15% for instance), this could be due to a **Chance event**. A chance event can happen due to any cause such as loss of follow up, death, travelling. It should be a small percentage to be considered as a **Chance Event**.

---

## Key 33

- **Sensitivity** = True Positive ÷ (True Positive + False Negative)
- **Specificity** = True Negative ÷ (True Negative + False Positive)

**Scenario**:

**A new test to detect DVT is called DTI has been tested.**

**70 patients with a positive DTI had a confirmed DVT on Ultrasound.**

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**70 patients with a negative DTI had a confirmed DVT on US.**

**300 patients with a negative DTI had an Ultrasound excluded DVT.**

**100 patients with a positive DTI had an Ultrasound excluded DVT.**

**What is the Sensitivity and the Specificity of this DTI test?**

70 patients with a positive DTI had a confirmed DVT on Ultrasound → true positive.

70 patients with a negative DTI had a confirmed DVT on US → false negative.

300 patients with a negative DTI had an Ultrasound excluded DVT → true negative.

100 patients with a positive DTI had an Ultrasound excluded DVT → false positive.

**Sensitivity** = True Positive ÷ (True Positive + False Negative)

= 70 / (70 + 70) = 70 / 140 = 0.5

To get a percentage, multiply X 100 → **sensitivity = 50%**

**Specificity** = True Negative ÷ (True Negative + False Positive)

= 300 / (300 + 100) = 300/400 = ¾ = 0.75

To get a percentage, multiply X 100 → **specificity = 75%**

---

**Key 34**

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**There are 500,000 people living in a city called Palso. In the past 5 years, 250 deaths occurred due to SARS. What is the mortality rate of SARS in Palso expressed per 1,000,000 per year?**

The mortality rate is the number of deaths in the population over a period of time.

√ 250 had died over **5 years**. The question asks about "per year".

So, we divide this number by 5 to get the total deaths **per year**.

250 / 5 = 50 deaths per year "In a population of 500,000"

√ Another thing, the population is **half a million** (500,000), and the question asks about the rate in **one million**.

Thus, double it:

50 X 2

= **100**

---

## Key 35 Number needed to harm

• **Def**. → The number of people who have to take a treatment in order for (1) of then to have an adverse effect accountable to this treatment.

• The adverse effect could be anything that harms, either simple or dangerous.

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◙ **Example: If the number needed to harm is 5 to 7. What does this mean?**

**This means** → For every 5-7 people who take this treatment, 1 would have an adverse reaction accountable to the treatment.

---

## Key 36 Terminology

1000 women underwent mammogram. 100 were +ve. These 100 underwent biopsy. 90 were found negative on biopsy and 10 of them were found to have cancer. Out of these 100, another 5 were found to have cancer when biopsied. There are another 3 women that were normal on the mammogram but later on found to have cancer (they tested -ve from the start).

- The best term for the 90 → **False positive**.

(They tested positive on the screening tool "mammogram" however, they tested negative on biopsy "the confirmatory tool". So, They tested positive falsely on the mammogram).

- The best term for the 10 → **True positive**.

(They tested positive on mammogram, then confirmed positive by biopsy. So, true positive).

- The best term for the 5 → **False negative**.

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(These 5 were among the 900 who tested negative from the start on the mammogram but by biopsy, they were positive. So, the mammogram showed them as negative falsely).

• The best term for the 3 → **False negative**.

(They were negative from the start but then found to have the condition. So, they were negative falsely.).

• When the value is giving a combination of false negatives and true negatives, it is called → **Test negative**.

*Questions in the real exam can have the same idea but of course with different scenarios and conditions. So, it is important to differentiate between these terms.*

---

## Key 37 Terminology

**Q1)** 5000 women were involved in a study to test a new breast cancer test. 500 of these women tested "positive" on this new breast test. 50 of these women who tested positive underwent further breast biopsy and showed negative results for breast cancer. 5 of the 4500 women who tested negative on the new breast test at

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the beginning underwent breast biopsy and showed positive results for breast cancer. What is the most appropriate term to describe the 50 women?

These 50 women showed (**positive**) result on the new breast test "screening".

However, by biopsy, which is the confirmatory method, they tested (**Negative**).

Therefore, they are **FASLELY POSITIVE**.

(They tested positive on a screening test, but this positivity was proved wrong "False" on the confirmatory investigation which is breast biopsy. So, this is a not real positive result. Ie, **false positive**).

---

**Q2)** Looking at the previous question (Question number 118). What is the most appropriate term to describe the 4500 women?

If we look at the question, it says that 5000 women were tested on a new breast test. Then it says that 500 of these 5000 tested (Positive) on the new breast test. This means that the remaining 4500 women tested (Negative) on this new breast test.

Later, these 4500 (who tested negative on the new breast test) underwent breast biopsy and 5 of them were found to be (positive). Which means that 4445 were true negatives. And these 5 were false negative.

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This means that the total 4500 women have **2 negative values**:

- **True negatives** (445 women). "Negative on both tests".
- **False negatives** (5 women). "Negative on the new test but Positive on biopsy".

When a number of people has **2 negatives** (one is true and the other is false)

This is called → **Test Negative**.

---

## Key 38 A scenario on a study design (type of the study)

2 groups of people are involved in a study. The first group that includes 700 people are already taking medication (A). The second group that includes 800 people have already been taking medication (B). All 1500 participants will be followed to investigate the outcome of the two medications over a period of 5 years. What is the most appropriate term for this study design?

A) Retrospective case-control study.

B) Prospective case-control study.

**C) Prospective cohort study.**

D) Randomised controlled study.

E) Cross-sectional study.

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• There is no “prospective” case-control study.

All case-control studies are only retrospective. (This excludes option B).

• It is obvious that the pattern of the study in the stem is “prospective” ie, looking at the FUTURE results. Not, retrospective which looks at the past.

(This excludes option A).

• Now, here is an important point to look at:

**Randomised controlled studies VS Prospective cohort Studies**

√ In prospective cohort studies, the study is observational only. This means we do not (intervene) by giving drugs or doing procedures. We only follow 2 groups of people in time to see the effects of their routine things on their future outcomes. This is happening here in this stem! Do not get fooled by “receiving medication A and B”! These medications are already being taken by the participants. They were not offered by the researchers. This means that this study is still observational, not interventional (experimental) like in randomised controlled study.

√ In randomised controlled study (Experimental/ Interventional), one group will be taking a drug, the other will be taking a placebo or a different drug. These drugs are offered by the study makers (the investigators) to so their effects on the groups with time. This is an intervention not just an observation. So, this is a randomised control study.

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Another important example of experimental studies (controlled trials) is to give one group incentives (eg, financial rewards) to make them use drug A, while group B is not receiving any incentives. This is an assigned intervention/ exposure. Therefore, this is an experimental (randomised/non-randomised controlled trial), not an observational study (cohort, case-control, cross-sectional).

**Example of Randomised control study:**

2 groups of smokers are followed over time. One group will be taking drug (A), while the other group will be taking Placebo. They are then followed over time to see who would develop lung cancer. Drug A and placebo are offered by the study makers → Randomised control trial. (Interventional).

---

## Key 39

### A scenario on calculating the number needed to treat (NNT)

- **The NNT is** the average number of patients who need to be treated to prevent one additional bad outcome**.**
- **(eg,** the number of patients that need to be treated for one of them to benefit compared with a control in a clinical trial**).**
- **It is also defined as the** inverse of the absolute risk reduction (ARR)
- **i.e., NNT = 1/ARR**

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- **ARR =** AR in Control (Placebo) group - AR in Test (Treatment) group

(ARC – ART)

- **AR (absolute risk)**

**=** the number of events (good or bad) in treated or control groups,

divided by (÷) the total number of people in that group.

**These equations are important to solve scenarios on NNT**

**Example:**

**A new drug for the prevention of ischemic stroke among smokers with hyperlipidemia had been tried in a clinical trial. Group A had been given this new medication. Group B received a placebo. Both groups were followed over 10 years. The results are shown below:**

| | Developed Ischemic Stroke | Did not develop ischemic stroke | Total |
|---|---|---|---|
| **Group A** | 17 | 83 | 100 |
| **Group B** | 22 | 78 | 100 |
| **Total** | 39 | 161 | 200 |

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**What is the number needed to treat for this new drug to prevent one ischemic stroke?**

## Answer:

Let's first gives the names:

Group **A** here is the **treatment** or the test group (T) [received the real drug].

Group **B** is the **control** group (C) [received the Placebo].

Now: NNT = **1 ÷ ARR**

So, we need to calculate the absolute risk reduction (ARR) first.

ARR = ARC – ART

So, we first need to calculate both ARC and ART so we can calculate ARR.

• **ARC** = the number of events in control group ÷ the total number in this group

(Control group here is group B)

So, **ARC** = 22 ÷ 100 = 0.22

• **ART** = the number of events in treatment group ÷ the total number in this group

(Treatment group here is group A)

So, **ART** = 17 ÷ 100 = 0.17

Now that we have both ARC and ART, we can calculate the ARR

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- **ARR** = **ARC** – **ART** = 0.22 – 0.17 = 0.05 (take care, it is 0.05, NOT 0.5)

Finally, we have ARR, thus, we can calculate NNT

- **NNT** = **1 ÷ ARR** = 1 ÷ 0.05 = **20**

(To make it easier, you can multiply both sides by X 100)

NNT = 100 ÷ 5 = 20

**So**, 20 patients needed to be treated with this new medication in order to prevent 1 ischemic stroke.

**Ie**, one person would benefit by not developing an ischemic stroke for every 20 people receiving the new drug over 10 years. (The less the NNT, the Better the drug)

---

## Key 40

## Calculating the Odds Ratio

- The main outcome measure in case-control studies is **odds ratio (OR)**.
- **Odds Ratio** = (a X d) ÷ (b X c)

It is like CROSS (X) in the table. see the example below.

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**Example:**

**A case control study is done on 290 men to see the risk of smoking on developing myocardial infarction with time. The result is shown below:**

| | Developed MI | Did not develop MI |
|---|---|---|
| **Smokers** | 60 | 80 |
| **Non-smokers** | 50 | 100 |

**Based on this study, what is the odds ratio of developing myocardial infarction among smoker men?**

## Answer:

- **Odds Ratio = (a X d) ÷ (b X c)**

| | Disease (cases) | No disease (control |
|---|---|---|
| **Exposed** | (a) 60 | (b) 80 |
| **Unexposed** | (c) 50 | (d) 100 |

- Odds Ratio = (a X d) ÷ (b X c)

= (60 X 100) ÷ (80 X 50)

= 6000 ÷ 4000 = (remove the zeros) = 6 ÷ 4 = 1.5

- (If it is difficult to know the result of 6 ÷ 4,

you can divide both sides by 2 to make it easier,

this will give you 3 ÷ 2. Now it is easier that 3 ÷ 2 = 1.5

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- So, the odds ratio is **1.5**.

---

**Key 41**

## Calculating the Positive and Negative Predictive Value

### Positive Predictive Value (PPV)

= The number of True Positive/ The number of the Total Positives.

| Symptom/Characteristic/Case Definition | | + | - |
|---|---|---|---|
| | + | A True Positives | B False Positives |
| | - | C False Negatives | D True Negatives |

Sensitivity = A/(A+C)

Specificity = D/(D+B)

Positive Predictive Value = A/(A+B)

Negative Predictive Value = D/(C+D)

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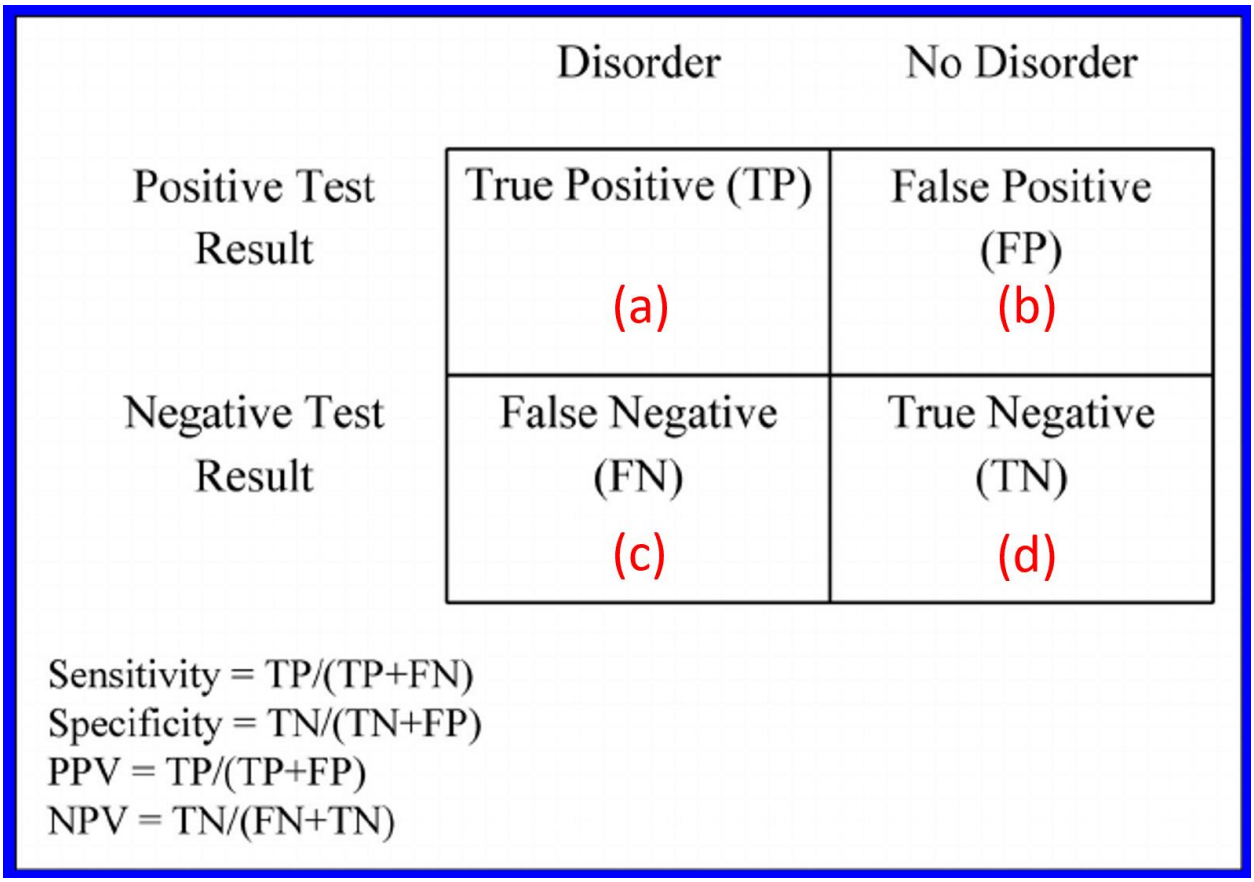


*Note, all these equations are important and any of them can be asked.*

*Sensitivity, specificity, PPV, NPV*

**Example (1)**:

Calculate the positive predictive value for the following study:

| | **Developed Ischemic Stroke** | **Did not develop ischemic stroke** | **Total** |
|---|---|---|---|
| **Group A** | 20 | 80 | 100 |
| **Group B** | 22 | 78 | 100 |
| **Total** | 39 | 161 | 200 |

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**PPV** = A/(A+B) = 20 ÷ (20+80) = 20 ÷ 100 = 2 ÷10 = 0.2

So PPV = 0.2 or 20% (multiply it by 100 to get it in %).

---

**Example (2)**:

A new test called (CoCT) has been developed to identify colon cancer. In the study, 60 people with positive CoCT had confirmed colon cancer on biopsy. 20 people with a negative CoCT had a confirmed colon cancer on biopsy. 400 people with negative CoCT has a biopsy that excluded colon cancer. 10 people with a positive CoCT had a biopsy that excluded colon cancer. What is the positive predictive value of CoCT test?

- PPV = TP ÷ (TP + FP)
- In this stem:

√ TP (true positive) ie, positive on both tests = 60

√ FP (false positive) ie, positive on the new, but negative on biopsy = 10

So, **PPV** = 60 ÷ (60 +10) = 60/70.

---

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**Example (3)**:

A study on 350 patients aged between 60-70 years was conducted to assess the diagnostic utility of BNP levels in the diagnosis of heart failure among patients presenting with shortness of breath. A BNP level of > 100 pg/mL was used as a diagnostic criterion for heart failure. Echocardiogram was performed on all patients to confirm the diagnosis. The number of positive patients with heart failure using BNP levels >100 pg/mL was 60 patients. Among those, the number of the patients who had been confirmed to have heart failure by echocardiogram was 55 patients. What is the positive predictive value (PPV) of BNP levels >100 pg/mL for diagnosing heart failure in this patient cohort?

**Positive Predictive Value (PPV)**

= The number of **True Positive**/ The number of the **Total Positives**.

True Positives (who were confirmed by echo) = 55.

Total positives (by both echo and BNP levels) = 60.

So,

PPV = 55/60

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(Note that **PPV = a/(a+b)**. However, in this scenario, they gave (a+b) which is the total positives as one number, which is 60 patients).

---

## Key 42 What is (p-value)?

• P-vale (probability value) determines if the result of a study or an experiment is statistically significant or not (should be taken seriously or not).

• It is a value between 0 and 1.

• A low p-value ($P < 0.05$) means that there is a low possibility that the results (outcomes) of this study were by luck.

I.e., the lower the p-value, the more real and true outcomes of a study.

**In other words:**

The lesser the p-value, the less it occurred just by coincidence, the **better** the study.

For example, P-value of 0.05 indicates that there is only 5% chance that the result of this study or experiment were just by luck.

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P-value (Probability value) means the probability that the results of an experiment are just by chance.

**Example (1)**: A study of a screening test has p-value of 0.4. What is the interpretation?

There is 40% probability (likelihood) that the results of this study are just by luck (by a chance). This is not a great study!

So, the remaining is 60%

→ This screening test is 60% effective.

Imagine that the p-value was 0.04 (not 0.4) → this would mean that the screening test is 96% effective (which is great)!

**Example (2)**: A study of a screening test has P-value of 0.1. What is the significance of this finding?

→ Evidence is **not** strong enough to suggest an existing effect.

- **P-value <0.05** → the study is statistically significant (and the lower the better. For example, p-value of 0.01 indicates very strong evidence).
- **P-value ≥0.1** → the study is statistically **NOT** significant (insignificant).

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## Key 43 What is (Lead time bias)?

• It is when you diagnose earlier than the occurrence of the death or the appearance of the symptoms. This would mistakenly increase the survival rate.

• Lead time bias happens **when survival time appears longer because diagnosis was done earlier** (for instance, by screening), irrespective of whether the patient lived longer.

**Example**:

A study is done on women to early detect breast cancer (using a new breast screening test). This study involved women with regular/ irregular/ screening and those who do not attend their periodic screenings. This study has started 5 years before these women had been diagnosed with breast cancer. It is noticed that the survival rates of all groups have improved (those who attend their screening program regularly and those who attend but irregularly and those who do not attend at all). What is the type of the bias in this study?

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→ Lead time bias.

The researchers have not extended the survival time, but instead, they have picked up the disease earlier so the survival rate had looked better with this new screening test.

---

## Key 44 Qualitative Research (Qualitative Study)

Qualitative research (study) involves collecting and analysing **non-numerical data** (e.g., text, video, or audio) to understand concepts, opinions, or experiences. It can be used to gather in-depth insights into a problem or generate new ideas for research.

Qualitative research is the opposite of quantitative research, which involves collecting and analysing numerical data for statistical analysis.

It is like an **interview** to discuss the experiences and opinions of a group of people about the efficacy of something on something.

**Example**:

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A study is conducted to test the efficacy of non-pharmacological methods on bipolar disorder. The researchers assembled and interviewed 20 bipolar disorder patients about their experience with these non-pharmacological treatment methods.

The type of the study is → Qualitative study.

---

## Key 45 "Sensitivity" interpretation

A screening test in the form of questionnaire was conducted to pick patients with depression. The total score of this questionnaire is 100. It is considered by the test that anyone scores 80 or more has depression and needs further appointments to confirm diagnosis. The sensitivity of this screening test is 0.75. What is the interpretation of this sensitivity?

→ 25% of patients with a score of less than 80 still have depression.

- **Sensitivity** identifies those who are truly **S**ick.
- **SpeciFicity** identifies those who are truly **F**it (well).

- **Sensitivity** ➔ ***The likelihood of a test reporting positive when the condition being tested is actually present.***

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So, when a test's sensitivity is 0.75 (ie, 75%), this means that there is still 25% of **false negative** patients. (They have the disease but the test failed to diagnose them. Ie, the test misses 25% of the patients).

**For the above example, another valid answer is straightforward:**

→ 75% of patients would have depression if they score > 80.

---

## Key 46 The Personal Risk of Developing Cancer

**Personal risk** = **Personal odds** (X) **Incidence**.

### Example:

A 56-year-old British man has personal odds of developing colorectal cancer equals 2.2 based on his strong family history of the disease and genetic studies. The incidence of colorectal cancer in the UK is 4%. What is his personal risk of developing colorectal cancer?

**Answer → 2.2 (X) 4 = 8.8%.**

---

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# Key 47

## Experimental Study (randomized or non-randomized)

**When there is an assigned exposure or intervention made by the investigator, it is an experimental study, not an observational study.**

**Remember**:

- **Experimental** studies include → randomised or non-randomised controlled trial.
- **Observational** studies include → case-control, cohort, cross sectional studies.

### Example:

2 groups of psychotic patients were given a new medication for psychosis. Patients in group A were receiving financial incentives to encourage them take the new drug while those in group B were not receiving any incentives. The study showed more adherence to medication in group A. What is the type of study?

Since there is an assigned intervention/ exposure (financial incentives here)

→ This is an **experimental**/ **interventional** study.

It could be a (**randomised**, or **non-randomised controlled trial**).

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# Key 48

## Experimental Study (randomized or non-randomized)

**When there is an assigned exposure or intervention made by the investigator, it is an experimental study, not an observational study.**

**Remember**:

- **Experimental** studies include → randomised.

## Study Design Scenario and Explanation

### Scenario:

A research team wants to study the impact of diet on the management of diabetes. They enroll 200 patients from various primary care practices within a city. Each practice is randomly assigned to either the intervention group, where patients receive personalized diet plans and regular nutritional counseling, or the control group, where patients receive standard dietary advice without personalized plans or additional counseling. The primary outcome is the change in HbA1c levels over 6 months.

### Which type of study design does this scenario best illustrate?

A. Cluster-randomized controlled trial

B. Cohort study

C. Cost-effectiveness analysis

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D. Case-control study

E. Cross-sectional study

**Answer → A.** Cluster-randomized controlled trial.

**Explanation:**

1. **Cluster-randomized controlled trial (**Correct** Answer)**:
- In this scenario, practices (clusters) are randomly assigned to either the intervention or control group, rather than individual patients. This design helps to prevent contamination, where patients in the same practice might influence each other's behavior if they were assigned to different groups. Randomizing at the cluster level also simplifies logistics and intervention delivery.

2. **Cohort study (**Invalid**)**:
- A cohort study follows a group of people over time to observe outcomes related to certain exposures. In this scenario, there is active randomization and intervention, making it an experimental study rather than an observational cohort study.

3. **Cost-effectiveness analysis (**Invalid**)**:
- Cost-effectiveness analysis compares the relative costs and outcomes (effects) of different courses of action. This scenario focuses on measuring the impact of a dietary intervention on clinical outcomes, not on comparing costs and benefits.

4. **Case-control study (**Invalid**)**:
- A case-control study compares patients with a condition (cases) to those without (controls) to identify factors that might contribute to the condition. This scenario

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involves an intervention and prospective measurement of outcomes, making it unsuitable for a case-control study design.

5. **Cross-sectional study (**Invalid**)**:
- A cross-sectional study analyzes data from a population at a single point in time. The given scenario involves following patients over a period (6 months) to measure changes, indicating a longitudinal design rather than a cross-sectional one.

---

# Key 49

**Relative Risk (RR) Calculation** (Repeated Topic).

## Scenario (1):

A longitudinal study investigates the relationship between sedentary lifestyle and the risk of developing coronary heart disease (CHD). The study encompasses 1000 individuals. Among those leading a sedentary lifestyle, 50 developed CHD, while 450 did not. Among those leading an active lifestyle, 10 developed CHD, and 490 did not. What is the relative risk (RR) of developing coronary heart disease for individuals with a sedentary lifestyle compared to those with an active lifestyle?

Detailed Answer:

**RR (Relative Risk) = (Incidence rate in the exposed group (*sedentary*)) / (Incidence rate in the unexposed group (*active*)).**

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First, we need to determine the incidence rates for both groups.

### 1. Incidence rate for the sedentary lifestyle group:

Incidence rate (sedentary) = Number of CHD cases in sedentary group / Total number in sedentary group
= 50 / 500 = 0.1

### 2. Incidence rate for the active lifestyle group:

Incidence rate (active) = Number of CHD cases in active group / Total number in active group
= 10 / 500 = 0.02

### Calculation of Relative Risk:

Now, we can calculate the relative risk:

RR = 0.1 / 0.02 = 5.

### Conclusion:

Therefore, the relative risk (RR) of developing coronary heart disease for individuals with a sedentary lifestyle compared to those with an active lifestyle is 5.

This means that individuals with a sedentary lifestyle have 5 times the risk of developing coronary heart disease compared to those with an active lifestyle.

---

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## How to Calculate 0.1 / 0.02 Without A Calculator? (2 Methods).

### Method (1): Using Fractions: "*complex method*".

1. Convert the decimals to fractions (optional):
- 0.1 can be written as 1/10.
- 0.02 can be written as 2/100 or 1/50.

2. Rewrite the division problem using fractions:
- 0.1 / 0.02 can be written as (1/10) / (1/50).

3. Invert the divisor and multiply:
- When you divide by a fraction, you can multiply by its reciprocal. The reciprocal of 1/50 is 50.
- So, (1/10) / (1/50) becomes (1/10) * 50.

4. Perform the multiplication:
- (1/10) * 50 = 5.

Therefore, 0.1 / 0.02 = 5.

### Alternative Method: Simple Division: "*simple method*".

1. Set up the division:
- 0.1 / 0.02 is the same as 0.1 ÷ 0.02.

2. Move the decimal points to make the divisor a whole number:
- Multiply both the numerator and the denominator by 100 to get rid of the

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decimals:
- 0.1 ÷ 0.02 becomes (0.1 × 100) / (0.02 × 100) = 10 / 2.

3. Perform the division:
- 10 ÷ 2 = 5.

So, 0.1 / 0.02 = 5.

---

## Scenario (2):

A cohort study investigates the relationship between smoking and the incidence of lung cancer. The study group consists of 200 individuals. Among those who smoke, 40 were diagnosed with lung cancer, and 60 were not. Among those who do not smoke, 10 were diagnosed with lung cancer, and 90 were not. What is the relative risk (RR) of developing lung cancer for individuals who smoke compared to those who do not smoke?

### Detailed Answer:

Step-by-Step Calculation of Relative Risk (RR):

**Step 1: Organize the data into a 2x2 table (~~not needed~~ if you can calculate directly).**

| | Lung Cancer (Yes) | Lung Cancer (No) | Total |
|---|---|---|---|
| Smokers | 40 | 60 | 100 |
| Non-Smokers | 10 | 90 | 100 |
| Total | 50 | 150 | 200 |

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To calculate the relative risk (RR), we use the following formula:

**RR Relative Risk** = **(Incidence rate in the exposed group (smokers)) / (Incidence rate in the unexposed group (non-smokers))**

## Step 2: Calculate the incidence of lung cancer in each group.

√ Incidence in the smokers' group = Number of lung cancer cases / Total in smokers group
Incidence in smokers group = 40 / 100 = 0.40

§ Incidence in the non-smokers group = Number of lung cancer cases / Total in non-smokers group
Incidence in non-smokers group = 10 / 100 = 0.10

## Step 3: Calculate the Relative Risk (RR).

RR = Incidence in smokers group / Incidence in non-smokers group
RR = 0.40 / 0.10 = 4

Therefore, the correct answer is → RR = **4**

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Explanation:

Relative Risk (RR) is a measure used in cohort studies to determine the strength of the association between an exposure (in this case, smoking) and an outcome (lung cancer). An RR of 4 indicates that individuals who smoke have four times the risk of developing lung cancer compared to individuals who do not smoke. This significant finding suggests a strong association between smoking and the incidence of lung cancer.

---

## Key 50

**Quick 3 Scenarios and Questions on Previous Topics** (*Important*).

### Scenario (1):

A clinical study is conducted to assess the efficacy of a new arthritis medication in preventing severe joint pain in high-risk patients. Patients were treated with the medication for 2 years, and the occurrence of severe joint pain was compared with a control group that did not receive the treatment.

| | Total | Had severe joint pain |
|---|---|---|
| Medication | 100 | 30 |
| No Medication | 100 | 60 |

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Based on these outcomes, what is the number needed to treat (NNT) to prevent one severe joint pain episode over 2 years?

**Options:**

A) 3.33.

B) 4.5.

C) 5.25.

D) 6.66.

E) 7.2.

---

**Answer: → A) 3.33.**

---

**Solution:**

√ **NNT** (Number Needed to Treat) = 1 / **ARR** (Absolute Risk Reduction).

√ **ARR** = **ARC** (absolute risk in the control group) – **ART** (absolute risk in the treatment group).

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√ **ARC** = 60/100 = 0.60.

√ **ART** = 30/100 = 0.30.

√ **ARR** = 0.60 – 0.30 = 0.30.

**NNT** = 1 / 0.30.

**NNT** = **3.33**.

So, the **Number Needed to Treat (NNT)** is **3.33**.

***So, for this scenario****:*

*For every **3.33 people treated with the new arthritis medication**, **1 episode of severe joint pain** is **prevented** over the study period of 2 years.*

*This means that you need to treat approximately 3 to 4 people to prevent 1 person from experiencing severe joint pain.*

---

**Extra: How to calculate 1 / 0.30 without a calculator?**

1. Start with 1 / 0.30 (where 0.30 is a decimal, a number that represents parts of a whole, using a decimal point).

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2. Multiply both the numerator (top) and the denominator (bottom) by 10 to get rid of the decimal:

   (1 × 10) / (0.30 × 10) = 10 / 3.

3. Now divide the fraction:

   10 / 3 = 3.33

---

## Scenario (2):

A clinical research study was carried out between 2020 and 2025 to examine the long-term impact of a specific chemotherapy drug used for treating lung cancer. The study involved 2,000 participants who had previously undergone surgery for lung cancer. Of these, 1,300 participants were already receiving this chemotherapy prior to the study's initiation, while 700 participants were either on alternative treatments or were not receiving chemotherapy. The study's primary goal was to observe the recurrence of lung cancer and survival rates over the five-year study period in both groups. Which of the following best describes the study design used in this research?

**Options:**

A) Qualitative study.

B) Cross-sectional study.

C) Prospective cohort study.

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D) Case-control study.

E) Randomised controlled trial.

---

**Answer:**

The correct answer is **C) Prospective cohort study**.

- **Explanation:**

  A **prospective cohort study** is a type of observational study where participants are grouped based on their exposure status (in this case, whether they were already receiving the chemotherapy or not) and followed over time to observe outcomes such as recurrence rates or survival. This design aligns perfectly with the scenario, as participants were already undergoing chemotherapy or not, and the study monitored them over a period of five years without interfering with their treatments.

  In a **case-control study**, participants are selected based on the presence (cases) or absence (controls) of an outcome, and the researchers look backwards to identify prior exposures. However, in this study, participants were selected based on their prior exposure to chemotherapy and followed forward in time to see if they developed the outcome (cancer recurrence or survival). This forward-

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looking aspect is key to distinguishing a prospective cohort study from a case-control study, which is retrospective in nature.

---

**Why the other options are invalid:**

A) **Qualitative study**.
A qualitative study involves collecting non-numerical data, often through interviews, focus groups, or observations about experiences, opinions, or behaviours. Since this study is focused on measurable outcomes (recurrence and survival rates), it is not a qualitative study but rather quantitative in nature.

B) **Cross-sectional study**.
A cross-sectional study assesses data at a single point in time. However, this scenario describes following participants for a five-year period to monitor their outcomes. A cross-sectional design does not involve this kind of long-term observation.

D) **Case-control study**.
In a case-control study, participants are selected based on whether they have a specific condition (cases) or do not (controls), and the study looks retrospectively at their exposure to risk factors. This does not fit the scenario since the participants in this study were followed forward in time, which is a defining feature of a cohort study, not a case-control study.

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E) **Randomised controlled trial**.

In a randomised controlled trial (RCT), participants are randomly assigned to treatment or control groups. In this study, however, participants were already on a treatment (or not) before the study began. There was no random assignment of participants to treatment groups, so this cannot be classified as an RCT.

---

**Important Notes:**

As described, **prospective cohort studies** are **observational** and are based on the **exposure status** without an intervention. There is no intervention in this scenario since the candidates were **already receiving chemotherapy** before the trial began.

In a **randomised controlled trial (RCT)**, the researchers actively intervene by **randomly assigning** participants to treatment or control groups. This means they decide who gets the treatment and who does not, creating an intentional **intervention**.

However, in this study, participants were **already receiving chemotherapy or not** before the study even started. The researchers did **not assign** the treatment for the sake of the study, so there was **no intervention** or random allocation of participants to different groups.

Since there was **no new treatment introduced** and **no random assignment**, this is not an RCT.

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Instead, this is an **observational study**, specifically a **prospective cohort study**, where the researchers follow participants based on their existing treatment status to observe outcomes over time.

Thus, **C) Prospective cohort study** best describes the design used in this research.

---

## Comparison Table of Epidemiological Study Designs:

| Study Type | Observational or Interventional? | Description | Example |
|---|---|---|---|
| **Qualitative Study** | Observational | Focuses on collecting non-numerical data (e.g., experiences, opinions) to understand behaviours or feelings. | Interviewing cancer patients to understand their emotional experiences during treatment. |
| **Cross-Sectional Study** | Observational | Examines data at a single point in time to identify associations between variables. | Surveying 500 people to check the relationship between exercise |

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| | | | |
|---|---|---|---|
| | | | and blood pressure today. |
| **Prospective Cohort Study** | Observational | Follows a group of people forward in time based on their exposure to observe outcomes. | Following smokers and non-smokers for 10 years to see who develops lung cancer. |
| **Retrospective Cohort Study** | Observational | Looks back at past data to measure outcomes after an exposure has occurred. | Reviewing old medical records to check if patients who took a specific medication had lower rates of heart attacks. |
| **Case-Control Study** | Observational | Compares people with a specific outcome (cases) to those without (controls) and looks back for exposures. | Comparing lung cancer patients with non-cancer patients to see if they smoked in the past. |

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| | | | |
|---|---|---|---|
| **Randomised Controlled Trial (RCT)** | Interventional | Participants are randomly assigned to treatment or control groups to measure the effect of an intervention. | Randomly assigning patients to take a new drug or a placebo and measuring its impact on blood pressure. |
| **Non-Randomised Controlled Trial** | Interventional | Participants are **not randomly assigned** to treatment or control groups. Instead, they are grouped based on certain characteristics (e.g., location, availability) or convenience. This introduces potential bias since groups are not created randomly, but the study is still considered experimental because the intervention is controlled by the researcher. | A study compares two hospitals—one hospital uses a new chemotherapy drug, and the other hospital continues with standard treatment. Patients are not randomly assigned to the hospitals; they are treated based |

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| | | | |
|---|---|---|---|
| | | | on where they were admitted. Researchers compare the outcomes between the two groups to assess the new drug's effectiveness. |

## Scenario (3):

A city has a population of 250,000 people. Over the past 4 years, 200 cases of liver cancer have been diagnosed. The local health authority seeks to determine the annual incidence rate of liver cancer per 1,000,000 people in this population. What is the annual incidence rate?

**Options**:

A) 100 per 1,000,000.

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B) 150 per 1,000,000.

C) 200 per 1,000,000.

D) 250 per 1,000,000.

E) 300 per 1,000,000.

---

**Solution:**

- The question asks for the **annual incidence rate** for a population of 1,000,000, but the city's population is 250,000.

  So, we will first need to calculate the **annual number of cases**.

- **Step 1**:

  The total number of cases over **4** years is **200**.

  To get the **annual number of cases**, we divide this by **4**:

  $200 \div 4 = 50$ cases per year.

- **Step 2**:

  The population given is **250,000**, but the question asks for the incidence rate **per 1,000,000** people.

  Since **250,000 is a quarter of 1,000,000**, we multiply by 4 to scale the result up to

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1,000,000:

50 × 4 = 200 cases per 1,000,000 people.

- The final **annual incidence rate** is therefore **200 per 1,000,000 people**.

---

**Answer:**

The correct **annual incidence rate** **is C) 200 per 1,000,000**.

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